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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,837	09/04/2001	Kenya Shitara	249-188	4386

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,837	Applicant(s) SHITARA ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 22-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/4/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Shitara *et al*

1. The amendment filed 3/10/2005 is acknowledged and entered into the record. Accordingly, claims 19-21,28, and 32 are canceled without prejudice or disclaimer.
2. Claims 1-18,22-27, and 29-31 are pending, claims 1-18 are withdrawn as being drawn to a non-elected invention. In the response filed 3/10/2005, applicant requests clarification on the examiner's "reminder" to cancel non-elected subject matter. Specifically, applicant indicates that in the office action mailed 10/2/2003, that "upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim."

Applicant is directed to MPEP 821.01 for clarification on the procedures regarding claims drawn to non-elected subject matter. The "reminder" was included for the purpose of compact prosecution. With regard to the consideration of generic claims, this statement only applies to claims containing multiple species (i.e. claim 24).

3. Claims 22-27 and 29-31 are examined on the merits. Claim 24 is examined to the extent that the claim reads on the elected species of KM1732.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The Information Disclosure Statement filed 9/4/2001 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Specification

6. The disclosure is objected to because of the following informalities:
- a. The specification is missing a brief description of the drawings.
- Appropriate correction is required.

Drawings

7. The drawings are objected to because there are two figure 1 drawings present within the specification. For example, the drawings filed 9/4/2001 and 10/31/2003 appear to be the same drawings and labeled figure 1, however, drawings filed 6/16/2004 are also indicated and labeled as "figure 1". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary

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to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New Arguments

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 22-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellamy *et al* (Cancer Res. 1999 Feb.; 59:728-733 - IDS 9/4/01) in view of Shitara *et al* (US Patent 6,617,160 - previously cited) and Rockwell *et al* (US Patent 5,840,301 - previously cited).

b. Bellamy *et al* teach that the VEGF receptor Flt-1 is expressed on neoplastic hematopoietic cells, and specifically on leukemic cells (see tables 1 and 2) and that this determination was made by using antibodies specific for Flt-1.

c. Bellamy *et al* do not specifically teach that the antibody would be effective for the treatment of leukemia, nor do they teach the administration of various types of antibodies, fragments thereof, or chimeric antibodies.

d. Shitara *et al* teach specific antibodies, (i.e. monoclonal, fragments, KM1732, and IgG1 isotype).

e. Rockwell *et al* teach that chimeric antibodies against VEGF receptor Flt-1 can be made (see in particular the claims)

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat leukemia in a patient in need thereof with

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an antibody specific against the VEGF receptor Flt-1. One of skill in the art would have been motivated to do so because Bellamy *et al* taught that leukemic cells expressed elevated of Flt-1 and that the suppression of VEGF receptors results in marked suppression of tumor growth. Moreover, both Shitara *et al* and Rockwell *et al* taught that various other antibodies to VEGF are available, such as the KN1732 antibody (which is specific for Flt-1), humanized antibodies to Flt-1 (see Rockwell claims), and that fragments of antibodies, such as Fabs, ScFv could also be used. One of skill in the art would expect reasonable success in doing so because Shitara *et al* showed that antibodies are effective at targeting to the Flt-1 receptor and Rockwell *et al* showed that antibodies to the Flt-1 receptor could be used for the treatment of cancer.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/10/2005.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "ChrispHX", with a stylized flourish at the end.

Christopher Yaen

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May 19, 2005